UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,884	06/09/2000	Erika Hawkins	341.014US1	1643

21186 7590 03/11/2003

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER
GITOMER, RALPH J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 15

Serial Number: 09/590,884
Filing Date: June 9, 2000
Appellant(s): Hawkins et al.

Robert J. Harris
For Appellant

EXAMINER'S ANSWER

This is in response to Appellant's Brief on Appeal filed August 27, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 1-57.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct, the after final amendment received 6/4/02 has not been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-57 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

JP 07067696 A	MITOMA et al.	3-1995
(both abstract and full translation provided)		
5,629,168	KRICKA	5-1997
5,814,471	WOOD	9-1998

(10) New Prior Art

No new prior art has been applied in this examiner's answer.

(11) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8-12, 16-21, 35-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mitoma.

Mitoma (JP 07067696 A) entitled ※Reducing Background Luminescence in the Detection of Heme and Peroxidase※ teaches in the abstract, a method of reducing background luminescence by treatment of heme and peroxidase with luminol and hydrogen peroxide in the presence of organic compounds such as citric acid which reduce background luminescence and increase sensitivity of measurement in the abstract. See in the translation page 9 column 2 regarding background luminescence. And on page 12 column 2 background luminescence is discussed where it may be suppressed. On page 14 Table 1, background luminescence may be suppressed by more than 80% by CyDTA.

Mitoma differs from the claims in that it does not expressly disclose an amount by which such background luminescence is reduced. Also Mitoma teaches a method of decreasing background luminescence in chemiluminescent reactions and not specifically in a method for decreasing background in a bioluminescent reaction.

It would have been obvious to one having ordinary skill in this art at the time the invention was made to reduce background luminescence from any source using an organic compound as taught by Mitoma because Mitoma teaches a general method of reducing background luminescence with specific organic compounds. It would additionally have been obvious to one having ordinary skill in this art to reduce background luminescence by a desired amount by utilizing an appropriate quantity of a selected organic

compound known to reduce such background luminescence.

Claims 1-3, 8-31, 34-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kricka.

Kricka (5,629,168) entitled ※Chemiluminescent Enhancers※ teaches the presence of specific organoboron compounds enhance chemiluminescence in the reaction involving luminol, hydrogen peroxide and peroxidase. Kricka discloses the presence of the organoboron compounds increases the signal/background ratio in chemiluminescent reactions and that improving the ratio is important in improving the sensitivity of the assay in column 3, lines 50-65. Kricka additionally discloses that the concentration of the enhancer as between 0.01 uM and 4 M in column 6, lines 25-31. Kricka teaches a kit including luminol, peroxidase and an organoboron enhancer in column 4 lines 58-60, and column 14 lines 19-33. Kricka further discloses that the signal/background ratio increased with increasing concentration of specific organoboron compounds in column 7, Table 1. Kricka teaches that the improvement in the ratio was attributable to the reduction in background light emission by specific organoboron compounds in column 8, lines 18-24.

Kricka does not expressly teach the reduction of background light emission from any specific source. Additionally, Kricka teaches a method for decreasing background luminescence in chemiluminescent reactions and does not specifically teach such a method in bioluminescent reactions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the method taught by Kricka for reducing background luminescence from any source and thus increase luminescent assay sensitivity since Kricka teaches a general process for increasing the signal/background ratio and decreasing background luminescence.

Claims 1-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wood.

Wood (5,814,471) entitled "Luciferase Inhibitor Compositions and Methods of Using Same" teaches a method for improving the kinetics of light production from luciferase activity. Wood discloses that the presence of thiol reagents including dithiothreitol results in a decrease in peak intensity and an increase in the total light emitted during a luciferase reaction in column 5 lines 52+ and column 8 lines 51-63. Wood discloses test kits including a luciferase-luciferin composition, ATP, a thiol reagent and a buffer solution which may be combined in a single container or in several containers in column 10 lines 39-67. Wood further discloses that a luciferase composition with

improved kinetics of light production includes an aqueous solution comprises beetle luciferase, CoA, a thiol reagent at a concentration between 10 and 1000 mM, and peak intensity reducing compounds in column 5 lines 37-45 and column 13 lines 24-35. Wood teaches that the luciferase assay may be conducted using cells in column 9 lines 32-48.

Wood does not expressly disclose that the sensitivity of the assay is increased by reducing luminescence due to autoluminescence, luminogenic molecules and independent of the presence of analyte. However, Wood does teach that the presence of thiol reagents results in a decrease in the peak intensity of light.

It would have been obvious to one having ordinary skill in this art to have utilized thiol reagents such as those taught by Wood to increase assay sensitivity since Wood teaches that thiol reagents decrease peak intensity and improve the kinetics of light production.

Further, Wood does not specifically disclose assays including Renilla luciferase or Cypridina luciferase, however, Wood does teach the use of beetle (firefly) luciferase and since both Renilla luciferase and Cypridina luciferase are well known in the art, it would have been obvious to one having ordinary skill in the art to have utilized either Renilla luciferase or Cypridina luciferase in the method taught by Wood for their known functions.

(12) New Ground of Rejection

This examiner's answer does not contain any new ground of rejection.

(13) Response to argument

35 U.S.C. 103(a) over Mitoma

Appellants argue that no motivation is proffered to modify Mitoma to yield a bioluminescent assay as presently claimed. The present invention reduces unwanted luminescence from non-bioluminescent sources without similarly reducing the desired signal. There are distinct classes of luminescent reactions. The peroxidase system taught by Mitoma catalyzes a single electron transfer where bioluminescent enzymes catalyze monooxygenation using molecular oxygen.

It is the examiner's position that Mitoma is directed to an assay in which luminescence occurs by the action of an enzyme on a substrate. Mitoma discloses that background luminescence is reduced by including compounds with specific functional groups in an assay in which a luminous reaction is measured in a peroxidase based reaction with a dihydrophthalazinedione derivative as a substrate. Since Mitoma does teach an assay in which luminescence is generated by the action of an enzyme, peroxidase, on a substrate, the dihydrophthalazinedione derivative, and Mitoma discloses specific chemical compounds that may be utilized to decrease background luminescence in such reactions, one having

ordinary skill in this art would certainly have had a reasonable expectation of success that background luminescence could be reduced using the compounds specifically disclosed by Mitoma. On page 12 column 2 Mitoma states background luminescence can be reduced and light emission from the enzyme reaction is not inhibited.

Regarding the above discussion about the distinction between luminescence as taught by the cited reference, bioluminescence as claimed in present claim 1 but not in other independent claims, and chemiluminescence, the following are how these terms are interpreted. On page 8 of the present specification, ※luminescent as used herein, includes bio-luminescence (i.e. light produced by a living organism), chemi-luminescence (light produced when a chemical reaction proceeds), and electrochemical luminescence.※ Therefor, the meaning of bioluminescence is interpreted to mean the emission of light from living organisms, where luminescence is simply production of light at low temperatures produced by chemical action, friction or electrical action; in this case chemical action.

Much of Appellants arguments are centered upon unclaimed limitations, such as distinguishing luminescence as taught by the cited references in contrast to presently claimed bioluminescence. It is respectfully submitted that in order for evidence of unexpected results to be sufficient to rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the claims. Present claim 2 and others are directed to luminescence. There are no structural requirements found in the claims that would limit them to any particular type of luminescence.

Furthermore, the 35 USC § 103 statute does not require that the prior art identically disclose or describe Appellants invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time this invention was made. It would appear there could be a genus/species issue at hand where the references teach the genus of luminescence and the claims are directed to a species of luminescence, bioluminescence.

35 U.S.C. 103(a) over Kricka

Appellants argue that as with Mitoma above, Kricka does not teach a bioluminescent assay. Regarding claim 13, such assays have been carried out in the presence of lysed cell extracts whereas the present claims are directed to whole cells.

It is the examiner's position that Kricka is directed to an assay in which luminescence occurs by the action of an enzyme on a substrate. Kricka discloses that background luminescence is reduced by including organoboron in an assay in which a luminescent reaction is measured in a peroxidase based reaction with luminol as a substrate. Since Kricka does teach an assay in which luminescence is generated by the action of an enzyme, peroxidase, on a substrate, luminol, and Kricka discloses organoboron compounds that may be utilized to decrease background luminescence in such reactions, one having ordinary skill in the art would certainly have had a reasonable expectation of success that background luminescence could be reduced using the compounds specifically disclosed by Kricka.

Regarding the difference between lysed cells and whole cells, one would have a high expectation of success in employing a known method for assaying lysed cells to assay whole cells.

35 U.S.C. 103(a) over Wood

Appellants argue that Wood does not suggest that unwanted luminescence can be reduced. And the present claims include limitations directed to selective quenching. Wood solves a different problem, improving the kinetics of light production.

It is the examiner's position that Wood is directed to inclusion of organic compounds in a bioluminescent reaction for the purpose of improving the kinetics of luminescence produced by a luciferase reaction. The present claims recite ▒a method for increasing the sensitivity of a bioluminescent assay comprising carrying out the assay in the presence of an organic compound...▒ The method disclosed by Wood is encompassed by such a method. Since Appellants have not provided any structural characteristics of the recited organic compound and merely discloses its functional characteristics, the method taught by Wood of including a thiol containing compound in a luciferase reaction in order to improve luminescence characteristics would obviate the method as claimed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

5

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

Michael G. Wityshyn
Supervisory Patent Examiner
Technology Center 1600

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600